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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,208	05/01/2001	Andrew Saxon	UC067.002A	6410

7590

03/22/2005

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EXAMINER
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HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/847,208

Applicant(s)

SAXON ET AL.

Examiner

Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 77,79-81 and 83-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 77,79-81 and 83-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/7/04.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/7/04 has been entered.
2. Claims 77, 79-81, and 83-96 are pending.
3. The drawings filed 12/7/04 are objected to because solid black shading is not permitted in Figure 9. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 77, 79-81 and 83-96 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 and 20-21 of copending Application No. 11/050,113. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claim 77 of instant application recites an isolated fusion molecule comprising a human IgG heavy chain constant region sequence capable of binding to a human IgG inhibitory receptor directly functionally connected to a human IgE heavy chain constant region sequence capable of binding to a human IgE receptor wherein said fusion molecule is capable of binding both the IgG inhibitory receptor and the IgE receptor (genus). Claim 1 of copending application 11/050,113 recites an isolated fusion molecule comprising a Fc $\epsilon$  fragment functionally connected at its carboxyl terminus to an Fc $\gamma$ 1 fragment (species). The species of fusion molecule in copending application 11/050,113 anticipates the genus of fusion molecule in instant claims. The human IgG heavy chain constant region sequence of instant application is the same as that of Fc $\gamma$ 1 fragment of copending application 11/050,113. The human IgE heavy chain constant region sequence of instant application is the same as that of Fc $\epsilon$  fragment of copending application 11/050,113. The term "comprises" in claims 2-13, and 15 of copending application 11/050,113 extends the Fc $\gamma$ 1 fragment and Fc $\epsilon$  fragment to include additional amino acids at either or both ends to include the full-length human IgG heavy chain constant region and the full-length human IgE heavy chain constant region sequence. The fusion proteins as set forth in claims 1-15 of copending application 11/050,113 are inherently capable of binding to a human IgG inhibitory receptor such as the low affinity Fc $\gamma$ RIIb (claim 83 of instant application) and the IgE receptors such as high-affinity Fc $\epsilon$ RI and low affinity Fc $\epsilon$ RII receptor (CD23) (claim 84 of instant application).

Claim 81 of instant application recites the fusion molecule comprising a human IgG heavy chain constant region sequence capable of binding to a human IgG inhibitory receptor

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directly functionally connected to a human IgE heavy chain constant region sequence capable of binding to a human IgE receptor wherein said fusion molecule is capable of binding both the IgG inhibitory receptor and the IgE receptor wherein said IgG heavy chain constant region sequence and IgE heavy chain constant region sequence are connected via a polypeptide linker of 15 to 25 amino acid residues (genus). Claim 16 of copending application 11/050,113 recites an isolated fusion molecule comprising a Fc $\epsilon$  fragment functionally connected at its carboxyl terminus to an Fc $\gamma$ 1 fragment wherein the Fc $\epsilon$  and the Fc $\gamma$ 1 polypeptide sequences are functionally connected via a linker (species). The species of fusion molecule in copending application 11/050,113 anticipates the genus of fusion molecule in instant claims. Further, the human IgG heavy chain constant region sequence of instant application is the same as that of Fc $\gamma$ 1 fragment of copending application 11/050,113. The human IgE heavy chain constant region sequence of instant application is the same as that of Fc $\epsilon$  fragment of copending application 11/050,113. These human IgG heavy chain constant region sequence and human IgE heavy chain constant region sequence are linked together via a linker.

Claim 86 of instant application recites an isolated fusion molecule comprising a human IgG heavy chain constant region sequence capable of binding to a human IgG inhibitory receptor directly functionally connected to a human IgE heavy chain constant region sequence capable of binding to a human IgE receptor wherein said fusion molecule is capable of binding to both the IgG inhibitory receptor and to the IgE receptor and wherein said IgG heavy chain constant region sequence consists of the hinge-CH2-CH3 portion of an IgG heavy chain constant region. Claim 14 of copending application 11/050,113 recites a fusion molecule comprising the polypeptide sequence CH $\epsilon$ 2- CH $\epsilon$ 3- CH $\epsilon$ 4- $\gamma$ hinge-CH $\gamma$ 2-CH $\gamma$ 3. The "hinge-CH2-CH3 portion of an IgG heavy chain constant region" of instant application is the same as "- $\gamma$ hinge-CH $\gamma$ 2-CH $\gamma$ 3" of the fusion molecule in copending application 11/050,113 while the human IgE heavy chain constant region sequence of instant application is the same as that of CH $\epsilon$ 2- CH $\epsilon$ 3- CH $\epsilon$ 4 of the fusion molecule in copending application 11/050,113. The same reasons apply to claims 89-90 and 96. Finally, the Fc region of IgG and IgE are inherently capable of forming disulfide bond to form a homodimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. No Claims allowed.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.
8. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

March 21, 2005

  
CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
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